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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,980	04/27/2001	Robert D. Juncosa	ORCH 0182 PUS	1649

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EXAMINER	
TAYLOR, JANELL E	
ART UNIT	PAPER NUMBER

1634
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	09/844980	Applicant(s)	Juncosa, R., et al
Examiner	Taylor, J.	Group Art Unit	1634

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

Responsive to communication(s) filed on 6-4-02

This action is FINAL.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

Claim(s) 9-23 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 9-23 is/are rejected.

Claim(s) _____ is/are objected to.

Claim(s) _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on _____ is approved disapproved.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

Notice of Reference(s) Cited, PTO-892

Notice of Draftsperson's Patent Drawing Review, PTO-948

Interview Summary, PTO-413

Notice of Informal Patent Application, PTO-152

Other Detailed Action

Office Action Summary

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims 9-13 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that 9, 14, 16, and 17 are all similar in scope. This is not found persuasive because the apparatuses of the other groups have different structures, which have different modes of operation. The method of claim 16 is also a separate group because, although groups I and III are related as a product and a process for use, the method may be practiced without the device, as not all of the elements of the device are required in the method claim.

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 9-13 are rejected under the judicially created doctrine of double patenting over claims 1-5 of U. S. Patent No. 6,225,109 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: an analysis device comprising: a housing; at least one glass slide member positioned in the housing; an elastomer member positioned in said housing and said housing urging said elastomer member into sealing arrangement with said at least one glass slide member, said elastomer member having at least one channel thereon, at least one inlet port and at least one outlet port; wherein materials entering said housing through said at least one inlet port are transported through said at least one channel and out through said at least one outlet port.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(e) the invention was described in–
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 9-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Soane et al. (USPN 6,176,962).

Soane et al. teaches enclosed microchannel structures. Soane teaches "In general, the microchannel structures according to the invention are constructed of two parts, each having a planar surface, sealed together so that the generally planar surfaces are opposed. One part is referred to as a base plate, and the other is referred to as the cover. The planar surface of the base plate includes one or more microchannels, while the planar surface of the cover may or may not include one or more microchannels." (Col. 4, lines 59-66). Soane also teaches "Any of a variety of microchannel patterns, device shapes, and substrate materials can be used to construct and assemble the components of the microfluidic systems according to the invention, so long as the device includes at least a generally planar base plate containing microchannels constructed of a plastic material...a base plate constructed of a plastic material, in which the microchannels are formed, can be covered with a glass plate to enclose the channels, and sealed with an elastomeric film of, for example, a silicon or polyurethane elastomer." (Col. 5, lines 16-27). The patent goes on to teach that the base plate may be made of polymethylmethacrylate (PMMA). (Col. 10). In figure 5, it is clear that the invention contains inlet and outlet ports, as are necessary for the transportation of fluids. Therefore, the patent teaches a housing (the structure), a glass slide member positioned in the housing (the glass cover), and an elastomer member

which is sealed to the cover, having channels thereon and an inlet and outlet port.

Therefore, all of the limitations of the instant claims are met.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 11, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soane et al., as disclosed above, and further in view of Wolk et al. (USPN 6,322,683).

Soane et al. teaches enclosed microchannel structures. Soane teaches "In general, the microchannel structures according to the invention are constructed of two parts, each having a planar surface, sealed together so that the generally planar surfaces are opposed. One part is referred to as a base plate, and the other is referred to as the cover. The planar surface of the base plate includes one or more microchannels, while the planar surface of the cover may or may not include one or more microchannels."

(Col. 4, lines 59-66). Soane also teaches "Any of a variety of microchannel patterns, device shapes, and substrate materials can be used to construct and assemble the components of the microfluidic systems according to the invention, so long as the device includes at least a generally planar base plate containing microchannels constructed of a plastic material...a base plate constructed of a plastic material, in which the microchannels are formed, can be covered with a glass plate to enclose the

channels, and sealed with an elastomeric film of, for example, a silicon or polyurethane elastomer." (Col. 5, lines 16-27). The patent goes on to teach that the base plate may be made of polymethylmethacrylate (PMMA). (Col. 10). In figure 5, it is clear that the invention contains inlet and outlet ports, as are necessary for the transportation of fluids. Therefore, the patent teaches a housing (the structure), a glass slide member positioned in the housing (the glass cover), and an elastomer member which is sealed to the cover, having channels thereon and an inlet and outlet port.

Soane does not teach that two glass slide members are provided, one on each side of said elastomer member, or that the elastomer member provides a tight seal on glass slide member without the need for adhesives, or that the base containing the microchannels is comprised of PDMS.

Wolk teaches multicomponent, microfabricated structures. "The body structure of the microfluidic devices described herein typically comprises an aggregation of two or more separate layers which when appropriately mated or joined together, form the microfluidic device of the invention, e.g., containing the channels and/or chambers described herein. Typically, the microfluidic devices described herein will comprise a top portion, a bottom portion, and an interior portion, wherein the interior portion substantially defines the channels and chambers of the device." (Col. 3, lines 11-20). Wolk goes on to teach that the upper and lower plates may be composed of glass. (Col. 3, line 40). Wolk also teaches that the substrate material may be PMMA or PDMS, among other materials. (Col. 3, lines 47-65). Wolk also teaches that "the upper

substrate is then overlaid and bonded to the upper surface of the lower substrate, whereby the grooves are sealed to form channels." (Col. 4, lines 3-8).

It would have been *prima facie* obvious to one of ordinary skill in the art to combine the teachings of Soane and those of Wolk. First of all, it would have been obvious that a glass slide may have resided on either side of the elastomer member. This is because it would have allowed for viewing of the fluids in the microfluidic chamber from either side, and it would have allowed for a seal to be formed with the channels on both the top and bottom, which would have prevented the loss of fluid. Secondly, it would have been obvious that the glass slide member may form a tight seal with the elastomer member without the need for adhesive. Materials such as PDMS were known to form tight seals with glass without the need for a sealant, and this would have allowed for lower cost and fewer process steps in the formation of the apparatus. Thirdly, it would have been obvious to use PDMS in place of the PMMA of Soane. This is because, as Wolk taught, these materials were interchangeable as microchannel plates. PDMS was readily manufactured using available microfabrication techniques, or from molding techniques. Furthermore, PDMS would have been preferred due to its ease of manufacture, low cost and disposability, and its general inertness to most extreme reaction conditions. (Col. 3, lines 55-65). Therefore, it would have been obvious to combine the teachings of Soane with those of Wolk.

Summary

Claims 9-13 are considered. Claims 9-13 are rejected under the judicially created doctrine of double patenting over claims 1-5 of U. S. Patent No. 6,225,109. Claims 9-10

are rejected under 35 U.S.C. 102(e) as being anticipated by Soane et al. Claims 11, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soane et al., as disclosed above, and further in view of Wolk et al. No claims are free of the prior art and no claims are allowable.

Conclusion

Any inquiries of a general nature relating to this application, including information on IDS forms, status requests, sequence listings, etc. should be directed to the Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland, whose telephone number is (703) 305-0273.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1634 via the PTO Fax Center using (703) 872-9306 or 872-9307 (after final). The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Janell Taylor Cleveland

July 9, 2002



W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600